

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Chapoulaud et al.	Art Unit: 3732
Serial No.	: 09/941,151	Examiner: Heidi Marie Eide
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For	: CUSTOM ORTHODONTIC APPLIANCE FORMING METHOD AND APPARATUS	

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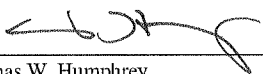
DECLARATION OF CRAIG ANDREIKO

I, Craig Andreiko, hereby declare and state as follows:

- 1) I am an employee of Ormco, the assignee of the above-noted patent application, and a practicing orthodontist.
- 2) I am one of the three inventors named in the above-noted patent application. I have reviewed the declaration of Mr. Eric Chapoulaud in connection with preparing this declaration. The paragraphs of this declaration are numbered to match those used in Mr. Chapoulaud's declaration.
- 3) This application is one of several applications derived from a provisional application filed by our attorneys in late 1999, relating to the work done at Ormco over the course of several years preceding those filings.

Certificate of Electronic Filing

I hereby certify that this correspondence and any enclosures are being send electronically via EFS-WEB to the United States Patent and Trademark Office on the date indicated below.


Thomas W. Humphrey
Reg. No. 34,353

4-21-2009
Date

- 4) The work that led to the provisional application filed in 1999, was known as the Elan project.
- 5) The following reviews the development history for various aspects of the Elan project, referencing documents attached to Mr. Chapoulaud's declaration. The documents establish the various points in time of the history provided below.
- 6) The Elan project featured the development of software having the purpose of designing customized brackets that could be fitted to the patient's teeth. The Elan software included an extensive graphical interface for imaging the shapes of teeth, selecting landmarks on the tooth shapes to define a desired tooth repositioning, and then creating customized brackets that would guide the teeth to the desired final positions.
- 7) In the original versions of the Elan software, developed up to the Summer of 1996, the brackets were customized for the desired tooth positions, by placing "vanilla", or slotless, brackets into a computer controlled milling machine, that would cut customized slots according to the desired tooth repositioning (the customization would involve establishing the torque to be applied by the archwire to the bracket, and the rotation, if any, to be achieved). This technique did not, however, permit the bracket pad to be customized to the tooth surface shape.
- 8) In the Summer of 1996, Eric Chapoulaud and I began working on methods to enable the Elan software to directly manufacture customized brackets using rapid prototyping technology. Ultimately, these efforts led to the conception of a method for creating customized brackets by a procedure involving stereolithographic printing, which is also

known in the literature as “three dimensional (3D) printing”. Bracket shapes were to be printed in wax, and then converted to metal casts using an investment casting method.

- 9) The stereolithographic or “3D printing” method for printing three dimensional structures was well developed at that time, and machines for creating three dimensional structures with this method were available on the market. This approach had not been applied to orthodontics up to that time, to my knowledge.
- 10) Furthermore, the investment casting method that would be used to create brackets from wax patterns, was well known at that time, and used on a daily basis within Ormco for the creation of orthodontic appliances. The use of investment casting had not been applied to creating bracket pads customized to tooth shapes up to that time, to my knowledge.
- 11) Exhibits A, B, C, D, E and F attached hereto document the development and prototyping of this customized bracket manufacturing method.
- 12) Exhibit A are photographs of a wax bracket dated June 18, 1996 and July 10, 1996. I recall Eric Chapoulaud making these brackets at the offices of the West Coast distributor of Sanders Prototype Inc. of Wilton, N.H., working with their sales personnel. The brackets were evaluated by Ormco and were generally well received as discussed below.
- 13) The July photograph in Exhibit A shows a part made only of green colored “structural” wax, which is the finished product. Immediately after the printing process, the green structural wax that forms the finished part, is encased in red colored “support” wax. The red support wax is washed away from the green structural wax after printing, to produce

the finished part. In the June photograph, a bracket with some remaining support wax (colored red) can be still be seen.

14) This test of the use of stereolithography to create orthodontic appliances was considered successful. Eric Chapoulaud pursued the matter further via a visit to Sanders' New Hampshire facility. The purpose of this visit was to discuss the stereolithographic equipment sold by Sanders and its adaptation for production line creation of customized orthodontic appliances, specifically, customized brackets. I recall this trip specifically, and I have no reason to question the details and documentation regarding this trip which are recited in paragraphs 15-17 of Mr. Chapoulaud's declaration.

17) I specifically recall that Elan software was used by Mr. Chapoulaud to be used in testing the feasibility of the Sanders machine for our purposes, and that parts made in Mr. Chapoulaud's experiments originated in the Elan software.

18) I specifically recall the trip report that is Exhibit E to Mr. Chapoulaud's declaration. At the bottom of the first page, Mr. Chapoulaud accurately describes the stereolithographic methods used by the Sanders equipment: as explained there, the machine "deposit[s] thermo-wax droplets in successive layers allowing the build of 3D Objects from ground up."

19) Exhibit E, at the top of the second page, details the use of structural wax and support wax to build parts in a layer-by-layer fashion, as explained above.

20) Exhibit E also confirms that Sanders had a machine known as the "Model Maker" available for purchase in November 1996, and had plans to introduce an upgraded

machine, the “Model Maker II”, in 1997. Ormco negotiated an arrangement to purchase the “Model Maker” and upgrade it to a “Model Maker II” when the new machine became available.

- 21) In the third page of Exhibit E Mr. Chapoulaud indicates his belief that he would be able to use the Elan programs that he had written, to create CAD models for direct fabrication of brackets with the Model Maker. I shared his belief, and agreed with the statement in the memo that “Using the 3D Modeler, we can design a software that creates completely the brackets, according to the particular dimensions of each tooth, and send these design [sic] to the Wax printer to create a master to use to cast the finished part. This is a new and specific application for Sanders.”
- 22) I recall the results of the further testing at Sanders documented in Exhibit E. On the third page it states “we have been able to manufacture a sample of two different one piece brackets that were designed by us. These parts are the most complex parts that we have asked Sanders to make. Most particularly, their pads includes [sic] a collection of little “pegs” of 0.015 x 0.015 inches. These are very little details that are correctly reproduced by the machine.”
- 23) I was involved in the preparation of Exhibit F to Mr. Chapoulaud’s declaration, which is a capital appropriation request submitted to request that Ormco allocate capital to purchase the Sanders Model Maker / Model Maker II for use in the Elan project. Exhibit F explains on the second and third pages that the Sanders machine had successfully created a three-dimensional bracket from a CAD design, and explains our anticipated use

of the Sanders machine in automated creation of completely customized brackets including customized bracket pads to fit to the tooth shape. Specifically, the document explains that the Elan software would be improved to allow customization of bracket pads to accomplish a further improvement over the existing methods.

- 24) The Exhibit F capital request explains on the first page that the Model Maker would permit the Elan software to be used to directly fabricate custom brackets rather than using a milling technique to customize the brackets.
- 25) Progress in development of the Elan software to create 3D models for brackets, and to control the Sanders machine, continued through early 1997. This progress is documented in the product development reports issued by Albert Ruiz-Vela, a manager at Ormco, which was copied to myself and the other inventors. The reports of Exhibits G, H, I, J, K, L and M report on activity from December 1996 through June of 1997.
- 26) Exhibit G illustrates (page 4) that in December 1996, Ormco was calibrating a scanner for the purpose of scanning tooth images which would be used in creating customized brackets and pads.
- 27) Exhibit H illustrates (page 4) that in January of 1997, Ormco had the scanner operational.
- 28) Exhibit I illustrates (page 4) that in February of 1997, a three dimensional scan of an upper jaw of a standard model ("P.K. THOMAS") was performed, and functions were developed in the Elan software to position CAD representations of standard "Spirit" brackets on the model of the scanned teeth. A set of brackets for an appliance was set-up on the model, and a wire to fit within those brackets was mathematically computed.

- 29) Exhibit J illustrates (page 4) that in March of 1997 a case of 5x5 brackets for the upper teeth of the P.K. THOMAS model was created “manually” using CAD software; the wire and the bracket positions and characteristics (torque, in/out and RIS) were developed as part of this process. Software for automating the wire design was specified.
- 30) Exhibit K illustrates (page 4) that in April of 1997 a plate was milled to thermoform the wire for the brackets defined in the previous month, and Jig design software was developed that would create bracket placement jigs for brackets. A prototype jig was milled for the upper right cuspid of the P.K. THOMAS case and was verified to have the correct precision.
- 31) Exhibit L illustrates (page 4) that in May of 1997, the Sanders machine arrived from New Hampshire, and was set up for use at Ormco. Also in that month, Ormco “[p]roduced wax parts of Upper Lateral brackets in different sizes: real life, scale 10 and currently scale 20.” The immediately following goals for June were to “produce customized wax patterns of brackets and JIGS, using the Elan Software.”
- 32) Exhibit M illustrates (page 4) that in June of 1997, “Software modules to create brackets from dimensions, torque, In/out and RIS was started [sic] from a previous prototype written in 1995”. While this Elan software was being developed, I “[c]ontinued producing parts with the [Sanders Model Maker software] MM6 Pro”.
- 33) At approximately this time (June 1997), Eric Chapoulaud was using a manual process to create customized brackets, using a “subtraction” method. Specifically, in the CAD software, a standard bracket pad was placed against the patient’s tooth, so that each point

in the outer perimeter of the pad was at or below the tooth surface. Thereafter, any portion of the bracket that was beneath the surface of the tooth was removed, to form a customized bracket pad shape.

34) While this process was effective to create model brackets that matched tooth crown surfaces, it resulted in bracket pads of uneven thickness. (A slide that is part of Exhibit N, which became Fig. 5G, clearly shows brackets with uneven pad thickness, that were created by the subtraction method described above.) This subtraction method was subsequently replaced with an automated and more robust method that created even bracket pad thickness, as noted below.

35) By May of 1997, a set of brackets had been cast from wax prototypes created by stereolithography with the Sanders machine. As stated in Exhibit L, the accomplishments of May of 1997 included “Produced wax parts of Upper Lateral brackets in different sizes: real life, scale 10 and currently scale 20.”

36) Thus, by May of 1997, Eric Chapoulaud, using Model Maker software, had produced a set of brackets mounted to jigs by the stereolithography – wax investment casting method.

37) In June of 1997, a set of jigs were created for an Upper Lateral bracket set. In Exhibit M, the June progress report, it is stated that “[a] set of 5x5 Jigs have been manufactured after accuracy improvement of the manufacturing software. These jigs have been manually mounted with to their respective brackets. The case reveals good fit accuracy to the model.”

38) During 1997, slides were taken for the purposes of presenting the progress of Elan.

Images from a set of these slides are attached as Exhibit N. Several of the figures of the provisional application filed in 1999 were derived from these slides, and the corresponding figure numbers are shown in Exhibit N.

39) Notably, among the slides in Exhibit N is a slide of the set of jigs created for the P.K.

THOMAS model in June of 1997. Specifically, the slide shows a set of jigs dated June 11, 1997. This slide became Figure 6A of the provisional application, although the figure does not include the June 11, 1997 date that was written on the original set of Jigs. This June 11, 1997 date is documentation of the prototypes for the P.K. THOMAS tooth model mentioned in Exhibit M, although the brackets are not attached to the jigs seen in the slide.

40) While the software development throughout this time was handled by Eric Chapoulaud, I have no reason to question his assertions in paragraph 40, that while he was creating customized jigs and manually creating brackets as described above, he was also refining the automated bracket creation software, first written in 1995, to automatically create brackets shaped for tooth surfaces. I recall his efforts in enhancing the software for automation continuing through June and into July 1997, and I also recall Mr. Chapoulaud attending training on the Sanders Model Maker during this time period.

41) I have reviewed the table referenced by Mr. Chapoulaud in his paragraph 41 and concur that Ormco successfully implemented or “reduced to practice” the methods recited in the claims of the application identified in that table.

42) I recall Eric Chapoulaud undertaking the activities in Exhibits O, P and Q in July of 1997 to develop and prepare the prototyped system for production. I specifically recall his return visit to Sanders in July 1997 mentioned in paragraph 43, the installation of the Model Maker II in July 1997 referenced in paragraphs 44-45 and Exhibits P and Q of Mr. Chapoulaud's declaration.

46) I recall that, as documented in Exhibit Q, Mr. Chapoulaud's custom software reached a level of completion where it could not only create customized brackets, but also create brackets in a "tree" form. Forming brackets in a tree allowed Ormco to create multiple brackets in a single cast. At this point, the software was considered both fully "developed and tested".

47) I recall, as documented in Exhibit Q, that Mr. Chapoulaud's software was complete and able to create customized bracket designs automatically. This is established by the statement that "The Bracket design has also been improved to include constant pad thickness, lower gingival wing, rounded corners on the pad". These enhancements and improvements refer to the replacement of the manual, "subtraction" method for custom formation of brackets, with an improved automated method in which pads of constant thickness, conforming to tooth shape, would be automatically created by software.

48) I further recall have confirmed from the documents that software for the automated creation of brackets with pads conforming to tooth shape, was developed and available at Ormco no later than the date of the Exhibit Q report, which is July 30, 1997. I recall Mr.

Chapoulaud and I working diligently on a daily basis through June and July of 1997 to develop this system, which was Mr. Chapoulaud's central work project at the time.

49) I concur with the correspondence between the claim language of U.S. Patent 09/941,151 and the system developed at Ormco as described above, which set forth in the table following paragraph 49 of Mr. Chapoulaud's declaration.

50) I recall, as documented in Exhibit R (page 4) that in August 1997, an automatic link was created between the software for computing an orthodontic set-up (desired bracket placement) and the software for making customized brackets. Further, using the integrated software, a new set of ten brackets for the upper teeth of the P.K. THOMAS case was calculated. Software was also built to form brackets into trees for investment casting. Further, a scan of the lower jaw of the P.K. THOMAS model was captured to allow the creation of a lower jaw bracket and jig set.

51) I recall, as illustrated in Exhibit S (page 4) that in September 1997, software for setup of a lower jaw was created, as a preliminary to creating brackets for the lower jaw of the P.K. THOMAS model. Further, the bracket trees defined in August 1997 were printed in wax for subsequent casting to validate that part of the process.

52) I recall, as set forth in Exhibit T (page 4) that in October 1997 software was developed to set up the lower (mandible) teeth automatically, using the scanned images of those teeth.

53) I also recall, as documented in Exhibits R, S and T, that by the end of 1997, software had been fully developed to (1) scan both upper and lower teeth to create a 3D model, (2) set-up the teeth for orthodontic correction, (3) automatically create 3D customized bracket

models from the set-up, and (4) automatically print the brackets in trees with the Sanders Model Maker II, so that the bracket trees could then be cast, and the brackets mated with jigs for installation on the teeth.

- 54) The visual interface of the software for this process is illustrated in the slides of Exhibit N. I recall defining, for Mr. Chapoulaud, the landmarking points on teeth that should be used in creating an orthodontic setup, which points are illustrated in these slides. These slides were collected for an Ormco presentation of the developed technology in late 1997. As noted above, they were the basis for the figures in the present application and thus provide the same visual presentation of tooth shapes that is disclosed in the application.
- 55) For the purpose of computing a set-up of teeth, the software would allow an operator to identify landmarks on the images of the teeth of a patient by interaction on the screen. Based on these landmark features, the software would compute an idealized set-up of the teeth, i.e., a corrected position for the teeth. I recall applying my skills in orthodontia to select landmarks on teeth for this process.
- 56) During the development of this software, in several instances Eric Chapoulaud would use the software to landmark tooth images, and I would also use the software to landmark the same tooth images. The purpose of this exercise was to test the software's usability and its repeatability from one use to the next, and to evaluate the extent to which orthodontist expertise would influence set-ups.
- 57) Exhibits U and V attached hereto are color printouts of one exercise of the type described above. Exhibit U illustrates landmarks selected by me on February 12, 1998, on a set of

tooth images. The consequent corrected tooth positions are also shown. In these printouts, the tooth surface images are not shown, however, the screen display could include or exclude tooth surface images. Exhibit V illustrates landmarks selected by Eric Chapoulaud on February 13, 1998, on the same tooth images as used by me in Exhibit U. It can be seen that the landmarks are somewhat different than those I chose, and the consequent corrected tooth positions are also different. Exhibit V includes the tooth surface images on a number of the printed pages.

58) I concur with the correspondence between the claim language of U.S. Patent 10/868,311 and the system developed at Ormco as described above, which set forth in the table following paragraph 58 of Mr. Chapoulaud's declaration, and the conclusion that the methods recited in those claims was implemented at least by the February 13, 1998 date of Exhibit U:

I declare under penalty of perjury that the foregoing is true and correct to the best of my information and belief.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'Craig Andreiko', with a long horizontal flourish extending to the right.

Craig Andreiko

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